

NOVARTIS AG
Form 6-K
June 18, 2008

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER

PURSUANT TO RULE 13a-16 or 15d-16 OF

THE SECURITIES EXCHANGE ACT OF 1934

Report on Form 6-K dated June 17, 2008

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

Lichtstrasse 35

4056 Basel

Switzerland

(Address of Principal Executive Offices)

Edgar Filing: NOVARTIS AG - Form 6-K

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F: ☒ **Form 40-F:** ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Yes: ☐ **No:** ☒

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Yes: ☐ **No:** ☒

Indicate by check mark whether the registrant by furnishing the information contained in this form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes: ☐ **No:** ☒

Novartis International AG
Novartis Global Communications
CH-4002 Basel
Switzerland
<http://www.novartis.com>

- Investor Relations Release -

Rasilez^{®(1)} ASPIRE HIGHER clinical program expands to 35,000 patients in 14 trials, the largest cardio-renal outcomes program ever

- *Novartis to study organ protection potential of Rasilez beyond documented ability to provide powerful blood pressure reductions that last beyond 24 hours^{(1),(2)}*
- *Three megatrials explore Rasilez benefits in difficult-to-treat patients with life-threatening co-morbidities – heart failure, cardiovascular events in elderly and diabetic kidney disease*
- *Data presented at Hypertension 2008 congress highlight impressive efficacy of Rasilez in managing high blood pressure in elderly, the fastest growing patient demographic segment with climbing healthcare costs^{(3),(4),(5)}*

Basel, June 17, 2008 Novartis today announced details of two new long-term outcome studies in its landmark ASPIRE HIGHER clinical trial program which has expanded to involve more than 35,000 patients in 14 trials. The series of trials that comprise ASPIRE HIGHER now form the largest and most far-reaching cardio-renal outcomes program worldwide.

The newly-launched studies will evaluate the organ protection potential of the first-in-class direct renin inhibitor Rasilez, known as Tekturna[®] in the US, for the treatment of heart failure and prevention of cardiovascular disease in the elderly, a patient segment that is predicted to more than double between 2000 and 2030⁽⁶⁾.

A third megatrial already under way is studying cardio-renal outcomes in diabetes.

High blood pressure is a sign that many organs in the body could be under threat⁽⁷⁾. Rasilez/Tekturna works by directly inhibiting renin, an enzyme that triggers a process leading to high blood pressure and organ damage. By inhibiting renin at the point of activation, Rasilez/Tekturna provides effective blood pressure reductions and may also afford greater protection against complications such as organ damage^{(8),(9)}.

One quarter of the world's population, or approximately one billion people, are now affected by high blood pressure. This figure is projected to rise to 1.56 billion by 2025, a 60% increase over the current figure⁽¹⁰⁾. In the US alone, the direct and indirect costs of high blood pressure in 2008 are estimated at USD 69.4 billion⁽¹¹⁾.

(1) Rasilez® is the trade name for aliskiren throughout the world, except in the US where it is known as Tekturna®.

Patients with hypertension, diabetes, kidney disease and heart failure continue to experience adverse clinical events despite current best treatment, said Professor John McMurray of the British Heart Foundation Cardiovascular Research Centre, University of Glasgow, Scotland.

The ASPIRE HIGHER program of clinical trials aims to build upon exciting proof of concept studies with aliskiren to evaluate the role of this new agent in reducing morbidity and mortality in these very common and important disease states.

The new morbidity and mortality studies were announced at Hypertension 2008, the congress of the European Society of Hypertension and International Society of Hypertension in Berlin. New data presented at the congress also demonstrate the benefits of Rasilez/Tekturna in lowering blood pressure in difficult-to-treat patient groups^{(3),(4),(5)}.

The ASPIRE HIGHER clinical program includes three major outcome studies:

- ALTITUDE will determine whether Rasilez/Tekturna, added to conventional therapy, delays heart and kidney complications in around 8,600 patients with type 2 diabetes at high risk for cardiovascular and renal events. The study began in late 2007 with completion anticipated by 2012.
- ATMOSPHERE will evaluate the effects of Rasilez/Tekturna on cardiovascular morbidity and mortality in patients with acute and chronic congestive heart failure on top of standard therapy.
- APOLLO will assess the effectiveness of Rasilez/Tekturna in preventing cardiovascular morbidity and mortality in elderly patients with or without high blood pressure and other risk factors.

In addition to these megatrials, the ASPIRE HIGHER program includes a comprehensive range of short-to-medium term studies to assess the potential organ protection benefits of Rasilez/Tekturna across a broad range of cardio-renal conditions including heart failure, post-acute coronary syndromes, post-myocardial infarction, left ventricular hypertrophy, coronary artery disease and diabetic nephropathy. Other studies are designed to further confirm the powerful blood pressure lowering effect of Rasilez/Tekturna.

ASPIRE HIGHER represents a major commitment to investigating this innovative therapy that can help physicians and patients better manage high blood pressure and its damaging effects, said Trevor Mundel, MD, Head of Global Development Functions at Novartis Pharma AG. Data already reported from the program have shown the potential for Rasilez to protect organs such as the heart and kidneys. We look forward to the results of these additional long-term outcome studies that we hope will demonstrate the benefits of Rasilez independent of its powerful blood pressure reductions.

Findings from three studies in the ASPIRE HIGHER program have already been reported. The AVOID study, published recently in *The New England Journal of Medicine*, showed that Rasilez/Tekturna reduced albuminuria, a key indicator of kidney disease, in type 2 diabetic patients with kidney disease and high blood pressure⁽¹²⁾.

The ALOFT study showed that treatment with Rasilez/Tekturna reduced a marker of heart failure severity called BNP⁽¹³⁾. The ALLAY study demonstrated that Rasilez/Tekturna reduced left ventricular hypertrophy (LVH), a marker of cardiac damage associated with an increased risk of cardiovascular events⁽¹⁴⁾. In ALLAY, the combination of Rasilez/Tekturna and the angiotensin receptor blocker (ARB) losartan achieved a numerically greater reduction in LVH than losartan alone, but the result was not statistically significant⁽¹⁴⁾.

Edgar Filing: NOVARTIS AG - Form 6-K

New data presented at Hypertension 2008 further demonstrate the blood pressure lowering benefits of Rasilez/Tekturna, particularly in difficult-to-treat patients^{(3),(4),(5)}.

A new *post hoc* analysis involving 1,124 patients showed that Rasilez/Tekturna 300 mg achieved significantly greater blood pressure control than hydrochlorothiazide (HCT) 25 mg in elderly patients aged 65 years or older (67.3% vs. 52.0% respectively), and numerically greater blood pressure control in the very elderly aged 75 years or older (80.0% vs. 52.6% respectively)⁽⁴⁾.

New data from another *post hoc* analysis in a subset of 338 patients with diabetes and stage 2 high blood pressure demonstrated that Rasilez/Tekturna 300 mg, both alone and in combination with the angiotensin-converting enzyme (ACE) inhibitor ramipril 10 mg, produced superior systolic and diastolic blood pressure lowering to ramipril 10 mg alone. At week eight the reductions were 19.7/11.0 mmHg, 21.7/12.9 mmHg and 14.9/8.6 mmHg respectively⁽⁵⁾. Stage 2 high blood pressure is a more severe stage of the disease where patients have systolic blood pressure at or above 160 mmHg.

Rasilez/Tekturna is approved in more than 45 countries. Tekturna was approved in the US in March 2007, and in the European Union in August 2007 under the trade name Rasilez. Tekturna HCT®, the first single-dose combination involving Tekturna, was approved in the US in January 2008. Rasilez/Tekturna was discovered by Novartis and developed in collaboration with Speedel.

Novartis is focused on improving the lives of the hundreds of millions of people with cardiovascular and metabolic diseases. As a global leader in cardiovascular and metabolic health for nearly 50 years, Novartis provides innovative therapies and support programs to treat high blood pressure and diabetes – both major public health issues.

The core of the Novartis portfolio is its cardiovascular medications for the treatment of high blood pressure and diabetes. These include the world's most-prescribed angiotensin receptor blocker, the first and only approved direct renin inhibitor, a single pill combining two leading high blood pressure medicines, and a novel DPP-4 inhibitor. Novartis is dedicated to helping physicians and patients improve cardiovascular and metabolic health through effective medicines, programs and an ongoing commitment to research.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as potential, will, predicted, could be, may, aims to, to evaluate, anticipated, designed to, can, look forward to, hope, or similar expressions, or by express or implied disclosure regarding potential new indications or labelling for Rasilez or regarding potential future revenues from Rasilez. Such forward-looking statements reflect the current views of the Company regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results with Rasilez to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Rasilez will be approved for any additional indications or labelling in any market. Nor can there be any guarantee that Rasilez will achieve any particular levels of revenue in the future. In particular, management's expectations regarding Rasilez could be affected by, among other things, unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; competition in general; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; government, industry and general public pricing pressures, and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected. Novartis is providing the information in this press

release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

About Novartis

Novartis AG provides healthcare solutions that address the evolving needs of patients and societies. Focused solely on growth areas in healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic pharmaceuticals, preventive vaccines and diagnostic tools, and consumer health products. Novartis is the only company with leading positions in these areas. In 2007, the Group's continuing operations (excluding divestments in 2007) achieved net sales of USD 38.1 billion and net income of USD 6.5 billion. Approximately USD 6.4 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 98,000 full-time associates and operate in over 140 countries around the world. For more information, please visit <http://www.novartis.com>.

References

- (1) Palatini P, Jung P, Schlyakhto E et al. Blood Pressure Reduction Following A Simulated Missed Dose Of Aliskiren, Irbesartan, or Ramipril: A Comparative Ambulatory Blood Pressure Monitoring Study. Poster Presentation at American Society of Hypertension 23rd Annual Scientific Meeting 2008 (Abstract 2351 ASH).
- (2) Oh BH, Mitchell J, Herron JR et al. Aliskiren, an Oral Renin Inhibitor, Provides Dose-Dependent Efficacy and Sustained 24-hour Blood Pressure Control in Patients with Hypertension. *J Am Coll Cardiol* 2007;49:1157-63.
- (3) Yarows S, Oparil S, Patel S, et al. Aliskiren in Combination with Valsartan Provides Additional Blood Pressure Lowering Effects Compared with Either Agent Alone in Elderly and Younger Patients with Hypertension. Poster presented at Hypertension 2008, Berlin.
- (4) Schmieder R, Philipp T, Guerediaga J, et al. Long-Term Aliskiren-Based Therapy Effectively Lowers Systolic Blood Pressure and Pulse Pressure in Elderly and Very Elderly Patients with Hypertension. Poster presented at Hypertension 2008, Berlin.
- (5) Uresin Y, Taylor AA, Kilo C et al. Aliskiren Monotherapy Lowers Blood Pressure More Effectively Than Ramipril Monotherapy in Patients with Diabetes and Grade 2 Hypertension: Subgroup Analysis of an 8-Week, Double-blind Trial. Poster Presented at Hypertension 2008, Berlin.
- (6) Sigg R. A Global Overview of Social Security in the Age of Longevity. Available at: [www.un.org/esa/population/meetings/EGMPopAge/](http://www.un.org/esa/population/meetings/EGMPopAge/Paper%206.pdf) Paper 6. Accessed 12 June 2008.
- (7) International Society of Hypertension. Frequently Asked Questions on Hypertension and its Treatment. Available at: <http://www.ish-world.com/default.aspx?FAQs>. Accessed 4 June 2008.
- (8) Müller D, Luft F. Direct Renin Inhibition with Aliskiren in Hypertension and Target Organ Damage. *Clin J Am Soc of Nephrol*. 1:22-228, 2006.
- (9) Shafiq MM, Menon DV, Victor RG. Oral Direct Inhibition: Premise, Promise, and Potential Limitations of a New Antihypertensive Drug. *Am J Med*. 2008 Apr;121(4):265-71.

- (10) Kearney P et al. Global Burden of Hypertension: Analysis of Worldwide Data. Lancet 2005;365:217-23.
- (11) Rosamond W, Flegal K, Furie K et al. Heart Disease and Stroke Statistics 2008 Update. A Report From the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Circulation 2008;117:e25-e146.
- (12) Parving H-H et al. Aliskiren Combined with Losartan in Type 2 Diabetes and Nephropathy. N Eng J Med June 5, 2008; 358:2433-46.
- (13) McMurray J, Pitt B, Latini R, et al. Effects of the Oral Direct Inhibitor Aliskiren in Patients with Symptomatic Heart Failure. Circulation: Heart Failure. 2008;1:17-24.
- (14) Solomon S, Appelbaum E, Manning WJ, et al. Effect of the Direct Renin Inhibitor Aliskiren, Either Alone or in Combination With Losartan, Compared to Losartan, on Left Ventricular Mass in Patients With Hypertension and Left Ventricular Hypertrophy: The Aliskiren Left Ventricular Assessment of Hypertrophy (ALLAY) Trial. Late Breaker presentation at American College of Cardiology 57th Scientific Sessions 2008.

###

Novartis Media Relations

Jeffrey Lockwood

Novartis Global Media Relations
+41 61 324 7999 (direct)
+41 79 618 7748 (mobile)
jeffrey.lockwood@novartis.com

Navjot Rai

Novartis Pharma Communications
+41 61 324 6498 (direct)
+41 79 777 6400 (mobile)
navjot.rai@novartis.com

e-mail: media.relations@novartis.com

Novartis Investor Relations

Ruth Metzler-Arnold

Katharina Ambuehl
Pierre-Michel Bringer
John Gilardi
Thomas Hungerbuehler
Isabella Zinck

+41 61 324 9980

+41 61 324 5316
+41 61 324 1065
+41 61 324 3018
+41 61 324 8425
+41 61 324 7188

North America Office

Richard Jarvis
Jill Pozarek
Edwin Valeriano

+1 212 830 2433
+1 212 830 2445
+1 212 830 2456

Central phone no:

+41 61 324 7944

Fax no:

+41 61 324 8444

e-mail: investor.relations@novartis.com

Fax no:

+1 212 830 2405

e-mail: investor.relations@novartis.com

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Novartis AG

Date: June 17, 2008

By: /s/MALCOLM B. CHEETHAM

Name: Malcolm B. Cheetham
Title: Head Group Financial
Reporting and Accounting